

FOR FURTHER INFORMATION CONTACT:

Linda A. Sherman, Advisory Committee Oversight and Management Staff (HF-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1220.

Dated: March 10, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Allergenic Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Allergenic Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held via videoconference and teleconference on April 8, 2003, from 1 p.m. to 3:30 p.m.

Location: Food and Drug Administration, Bldg. 29B, conference rm. A, 8800 Rockville Pike, Bethesda, MD. This meeting will be held by video and teleconference. The public is welcome to attend the meeting at the onsite location. A speaker phone will be provided for public participation.

Contact Person: William Freas or Jane Brown, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12388. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will listen to updates on FDA activities relating to allergen extract standardization.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 3, 2003. Oral

presentations from the public will be scheduled between approximately 2:15 p.m. and 3:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 4, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact William Freas, or Jane Brown at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 10, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

National Mammography Quality Assurance Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: National Mammography Quality Assurance Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 28, 2003, from 9 a.m. to 6 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Charles Finder, Center for Devices and Radiological

Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12397. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will receive information on the reauthorization of the Mammography Quality Standards Act (MQSA) and will discuss the potential impact of reauthorization on the current regulations particularly as it relates to personnel competency. The committee will also discuss mechanisms to recruit and retain mammography personnel as well as the latest draft and final MQSA compliance guidance changes. The committee will receive updates on approved alternative standards, the status of accreditation and certification of full field digital mammography, current inspection follow-up actions, and an overview of inspection observations. The MQSA compliance guidance documents, which are in a question and answer format, are available to the public on the Internet at <http://www.fda.gov/cdrh/mammography>. This guidance is being updated continually in response to questions that FDA receives from the public.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 31, 2003. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m. on April 28, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 31, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

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